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*Committee on the Environment, Public Health and Food Safety*

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**2016/0404(COD)**

13.10.2017

## **OPINION**

of the Committee on the Environment, Public Health and Food Safety

for the Committee on the Internal Market and Consumer Protection

on the proposal for a directive of the European Parliament and of the Council  
on a proportionality test before adoption of new regulation of professions  
(COM(2016)0822 – C8-0012/2017 – 2016/0404(COD))

Rapporteur: Françoise Grossetête

PA\_Legam

## SHORT JUSTIFICATION

The Commission plans to introduce a structured procedure for a proportionality test to be applied to the new provisions adopted by the Member States for framing their regulated professions.

Given the public service nature of the work done by healthcare professionals, the specific nature of which, in the rapporteur's view, is not sufficiently taken into account in the draft directive, the draft decision proposes excluding such professions from the scope of this text.

The opinion acknowledges the Commission's objective and the fact that the proportionality requirement set out in Article 59 of Directive 2005/36/EC on the recognition of professional qualifications also applies to measures regarding healthcare professionals. However, it considers the provisions of the directive to be sufficient and that they should not be made more complicated by introducing a systematic, ex-ante proportionality test.

The rapporteur is aware of the problems experienced by some Member States with implementing the proportionality principle and understands the Commission's wish to clarify the rules. In this case, however, and with regard to healthcare professionals and the need to protect public health, she considers that the Commission's proposals would be too complex to implement and would involve too much red tape. It would be wrong to adopt such restrictive horizontal legislation to resolve specific problems.

## AMENDMENTS

The Committee on the Environment, Public Health and Food Safety calls on the Committee on the Internal Market and Consumer Protection, as the committee responsible, to take into account the following amendments:

### Amendment 1

#### Proposal for a directive

#### Recital 7 a (new)

*Text proposed by the Commission*

*Amendment*

***(7a) There is a need to ensure that the Member States fulfil to the letter their responsibilities, set out in Article 168 of the Treaty on Functioning of the European Union (TFEU), regarding the details of their health policies and how they organise the provision of healthcare services and medical care by dedicated, regulated professions. In order to achieve***

*that result, such regulated professions should be excluded from the scope of this Directive.*

## Amendment 2

### Proposal for a directive Recital 9

*Text proposed by the Commission*

(9) The burden of proof of justification and proportionality lies on the Member States. The reasons for regulation invoked by a Member State by way of justification should thus be accompanied by an analysis of the appropriateness and proportionality of the measure adopted by that State and by specific evidence substantiating its arguments.

*Amendment*

(9) The burden of proof of justification and proportionality lies on the Member States. The reasons for regulation invoked by a Member State by way of justification should thus be accompanied by an analysis of the appropriateness and proportionality of the measure adopted by that State and by specific evidence substantiating its arguments. ***That should not prevent Member States from taking immediate measures in the field of health care which they consider necessary in order to protect public health.***

## Amendment 3

### Proposal for a directive Recital 12

*Text proposed by the Commission*

(12) Where the taking-up and pursuit of certain employed or self-employed activities are conditional on complying with certain provisions relating to specific professional qualifications, laid down directly or indirectly by the Member States, it is necessary to ensure that such provisions are justified by public interest objectives, such as those within the meaning of the ***Treaty***, namely public policy, public security and public health or by overriding reasons of general interest, recognised as such in the case-law of the Court of Justice. It is important to ensure

*Amendment*

(12) Where the taking-up and pursuit of certain employed or self-employed activities are conditional on complying with certain provisions relating to specific professional qualifications, laid down directly or indirectly by the Member States, it is necessary to ensure that such provisions are justified by public interest objectives, such as those within the meaning of the ***TFEU***, namely public policy, public security and public health or by overriding reasons of general interest, recognised as such in the case-law of the Court of Justice. ***Where those objectives***

that public interest objectives are adequately identified in order to determine the intensity of the regulation. For example, in order to ensure a high level of protection of public health, Member States should *enjoy* a margin of discretion to decide on the degree of protection which they wish to afford to public health and on the way in which that protection is to be achieved. It is also necessary to clarify that among the overriding reasons of general interest, recognised by the Court of Justice, are preserving the financial equilibrium of the social security system; the protection of consumers, recipients of services and workers; the safeguarding of the proper administration of justice; fairness of trade transactions; combating fraud and prevention of tax evasion and avoidance; road safety; the protection of the environment and the urban environment; the health of animals; intellectual property; the safeguarding and conservation of the national historic and artistic heritage, social policy objectives and cultural policy objectives. According to settled case-law, purely economic reasons, having essentially protectionist aims, as well as purely administrative reasons, such as carrying out controls or gathering statistics cannot constitute an overriding reason of general interest.

*apply, regulation of professions should be considered to be a necessary safeguard of the public interest rather than an obstacle to competition and free movement.* It is important to ensure that public interest objectives are adequately identified in order to determine the intensity of the regulation. For example, *account should be taken of the fact that people's health and lives are of prime importance among the assets and interests protected by the TFEU.* In order to ensure a high level of protection of public health, Member States should *be granted* a margin of discretion to decide on the degree of protection which they wish to afford to public health and on the way in which that protection is to be achieved. It is also necessary to clarify that among the overriding reasons of general interest, recognised by the Court of Justice, are preserving the financial equilibrium of the social security system; the protection of consumers, recipients of services, *including patients*, and workers; the safeguarding of the proper administration of justice; fairness of trade transactions; combating fraud and prevention of tax evasion and avoidance; road safety; the protection of the environment and the urban environment; the health of animals; intellectual property; the safeguarding and conservation of the national historic and artistic heritage, social policy objectives and cultural policy objectives. According to settled case-law, purely economic reasons, having essentially protectionist aims, as well as purely administrative reasons, such as carrying out controls or gathering statistics cannot constitute an overriding reason of general interest.

#### **Amendment 4**

##### **Proposal for a directive Recital 12 a (new)**

*Text proposed by the Commission*

*Amendment*

*(12a) Where regulation of a profession is justified by the protection of public health, the special characteristics of health services should be borne in mind. Health services are very different from other services, and patients are very different from other service recipients. As a result, it should be assumed that health professions are typically subject to regulation of professions.*

## **Amendment 5**

### **Proposal for a directive Recital 12 b (new)**

*Text proposed by the Commission*

*Amendment*

*(12b) This Directive seeks to strike a balance between securing public interest objectives and quality of services on the one hand, and improving access to, and exercise of, regulated professions, which is in the interests of the professionals themselves, on the other. It is for the Member States to determine the level of protection which they wish to afford to the public interest objectives and the proportionate way in which that level is to be achieved. It is clear from settled case law of the Court of Justice that when one Member State imposes less strict rules than another Member State, that does not necessarily mean that the stricter rules are disproportionate.*

## **Amendment 6**

### **Proposal for a directive Recital 18**

*Text proposed by the Commission*

*Amendment*

(18) The economic impact of the measure, including a cost-benefit analysis with particular regard to the degree of competition in the market and the quality

(18) The economic impact of the measure, including a cost-benefit analysis with particular regard to the degree of competition in the market and the quality

of the service provided, as well as the impact on the right to work and on the free movement of persons and services within the Union should be duly taken into account by the competent authorities. Based on this analysis, Member States should ascertain, in particular, whether the extent of the restriction of access to or pursuit of regulated professions within the Union is proportionate to the importance of the objectives pursued and the expected gains.

of the service provided, as well as the impact on the right to work and on the free movement of persons and services within the Union should be duly taken into account by the competent authorities. ***However, none of those prerogatives should take precedence over public safety, which remains paramount.*** Based on this analysis, Member States should ascertain, in particular, whether the extent of the restriction of access to or pursuit of regulated professions within the Union is proportionate to the importance of the objectives pursued and the expected gains.

## **Amendment 7**

### **Proposal for a directive Recital 20 a (new)**

*Text proposed by the Commission*

*Amendment*

***(20a) According to Article 168(1) TFEU a high level of human health protection should be ensured in the definition and implementation of all Union policies and activities. That also implies that a high level of human health protection is to be ensured when the Union adopts acts under other TFEU provisions.***

## **Amendment 8**

### **Proposal for a directive Recital 20 b (new)**

*Text proposed by the Commission*

*Amendment*

***(20b) The introduction of additional requirements could add value to the public interest objective and the fact that their combined effect should be assessed does not mean that those requirements are disproportionate. For example, continuous professional development requirements might be suitable for the***

*purpose of ensuring that professionals keep abreast of developments in their respective areas, while contributing to safe practice in professions with particular risks. In addition, continuous professional development requirements might be suitable where they cover technical, scientific, regulatory and ethical developments, and where they motivate professionals to participate in lifelong learning relevant to their profession. Where it is necessary and suitable to achieve the public interest objective, compulsory chamber membership could be considered to be appropriate, in particular where chambers have a public mandate.*

## **Amendment 9**

### **Proposal for a directive Recital 20 c (new)**

*Text proposed by the Commission*

*Amendment*

*(20c) This Directive should respect the Member States' competence to regulate professions in the field of health care based on Article 168(7) TFEU as well as Member States' intention to provide and guarantee a high level of health care and patient safety. For this purpose, Member States should be able to decide on the degree of importance of economic considerations in relation to the other relevant proportionality criteria.*

## **Amendment 10**

### **Proposal for a directive Recital 20 d (new)**

*Text proposed by the Commission*

*Amendment*

*(20d) The proportionality criteria as set out in this Directive could be applied to the appropriate extent and degree of*



*intensity during an assessment of proportionality undertaken before introducing new provisions, or before amending existing ones. The extent and degree of intensity applied during the assessment should be proportionate to the content of the provision being introduced and to its impact.*

## Amendment 11

### Proposal for a directive Recital 24

#### *Text proposed by the Commission*

(24) Since the objectives of this Directive, namely the removal of disproportionate restrictions on access to or pursuit of regulated professions cannot be sufficiently achieved by the Member States but can rather, by reason of the scale of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives,

#### *Amendment*

(24) Since the objectives of this Directive, namely the removal of disproportionate restrictions on access to or pursuit of regulated professions cannot be sufficiently achieved by the Member States but can rather, by reason of the scale of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of ***non-discrimination, and with the principle of*** proportionality as set out in that Article, this Directive does not go beyond what is necessary, in order to achieve those objectives,

## Amendment 12

### Proposal for a directive Article 1 – paragraph 1

#### *Text proposed by the Commission*

This Directive lays down rules on a common framework for conducting proportionality assessments before introducing new legislative, regulatory or administrative provisions restricting access to or pursuit of regulated professions, or amending existing ones, with a view to

#### *Amendment*

This Directive lays down rules on a common framework for conducting proportionality assessments before introducing new ***essential*** legislative, regulatory or administrative provisions restricting access to or pursuit of regulated professions, or amending existing ones,

ensuring the proper functioning of the internal market.

with a view to ensuring the proper functioning of the internal market, *while also ensuring that the protection of citizens through the use of verified standards and qualifications of all those regulated professions and professionals, remains of paramount importance. It does not affect the Member States' prerogative and discretion to decide whether and how to regulate a profession within the limits set by the principles of non-discrimination and proportionality.*

#### *Justification*

*In order to respect the principle of subsidiarity, to avoid additional bureaucracy and to be “proportional” the proportionality assessments have to focus on only essential modifications.*

### **Amendment 13**

#### **Proposal for a directive Article 2 – paragraph 1**

##### *Text proposed by the Commission*

1. This Directive shall apply to requirements under the legal systems of the Member States restricting access to a regulated profession or its pursuit, or one of its modes of pursuit, including the use of professional titles and the professional activities allowed under such title, falling within the scope of Directive 2005/36/EC.

##### *Amendment*

1. This Directive shall apply to requirements under the legal systems of the Member States restricting access to a regulated profession or its pursuit, or one of its modes of pursuit, including the use of professional titles and the professional activities allowed under such title, falling within the scope of Directive 2005/36/EC, *without prejudice to paragraph 1a of this Article.*

### **Amendment 14**

#### **Proposal for a directive Article 2 – paragraph 1 a (new)**

##### *Text proposed by the Commission*

##### *Amendment*

*1a. This Directive shall not apply to any requirements restricting access to, or to the pursuit of, regulated health professions in relation to the provision of*

*healthcare services, including pharmaceutical services and the prescription, dispensation and provision of medicinal products and medical devices, whether or not they are provided via healthcare facilities, and regardless of the ways in which they are organised and financed at national level or whether they are public or private.*

## **Amendment 15**

### **Proposal for a directive Article 4 – paragraph 1**

*Text proposed by the Commission*

1. Member States shall ensure that before introducing new legislative, regulatory or administrative provisions restricting access to or pursuit of regulated professions, or amending existing ones, the relevant competent authorities undertake an assessment of their proportionality in accordance with the rules laid down in this Directive.

*Amendment*

1. Member States shall ensure that before introducing new legislative, regulatory or administrative provisions restricting access to or pursuit of regulated professions, or amending existing ones, the relevant competent authorities undertake an assessment of their proportionality in accordance with the rules laid down in this Directive, *taking full account of the specific nature of each profession.*

## **Amendment 16**

### **Proposal for a directive Article 4 – paragraph 3**

*Text proposed by the Commission*

3. The reasons for considering that a provision is justified, necessary and proportionate shall be substantiated by qualitative and, wherever possible, quantitative evidence.

*Amendment*

3. The reasons for considering that a provision is justified, necessary and proportionate shall be substantiated by qualitative and, wherever possible *and relevant*, quantitative evidence.

## **Amendment 17**

### **Proposal for a directive Article 5 – paragraph 1**

*Text proposed by the Commission*

1. Member States shall ensure that legislative, regulatory or administrative provisions restricting access to or pursuit of regulated professions they intend to introduce and amendments they intend to make to existing provisions are justified by public interest objectives.

*Amendment*

1. Member States shall ensure that legislative, regulatory or administrative provisions restricting access to or pursuit of regulated professions they intend to introduce and amendments they intend to make to existing provisions are justified by public interest objectives, ***including the objective of public health and safety.***

**Amendment 18**

**Proposal for a directive  
Article 5 – paragraph 2**

*Text proposed by the Commission*

2. The relevant competent authorities shall consider in particular whether those provisions are objectively justified on the basis of public policy, public security or public health, or by overriding reasons in the public interest, such as preserving the financial equilibrium of the social security system, the protection of consumers, recipients of services and workers, the safeguarding of the proper administration of justice, fairness of trade transactions, combating fraud and prevention of tax evasion and avoidance, road safety, the protection of the environment and the urban environment, the health of animals, intellectual property, the safeguarding and conservation of the national historic and artistic heritage, social policy objectives and cultural policy objectives.

*Amendment*

2. The relevant competent authorities shall consider in particular whether those provisions are objectively justified on the basis of public policy, public security or public health, or by overriding reasons in the public interest, such as preserving the financial equilibrium of the social security system, the protection of consumers, recipients of services, ***including patients,*** and workers, the safeguarding of the proper administration of justice, fairness of trade transactions, combating fraud and prevention of tax evasion and avoidance, road safety, the protection of the environment and the urban environment, the health of animals, intellectual property, the safeguarding and conservation of the national historic and artistic heritage, social policy objectives and cultural policy objectives.

**Amendment 19**

**Proposal for a directive  
Article 6 – paragraph 2 – introductory part**

*Text proposed by the Commission*

2. When assessing the necessity and

*Amendment*

2. When assessing the necessity and

the proportionality of the provisions, the relevant competent authorities shall consider in particular:

the proportionality of the provisions, the ***competent authorities shall apply the criteria listed in this paragraph taking into account the particular circumstances of the profession concerned, the nature of the provision and the public interest objective pursued. The relevance of any individual criterion may therefore depend upon the importance of the public interest objectives pursued.*** The relevant competent authorities shall consider in particular:

## Amendment 20

### Proposal for a directive Article 6 – paragraph 2 – point a

*Text proposed by the Commission*

(a) the nature of the risks related to the public interest objectives pursued, in particular the risks to consumers, ***to*** professionals or third parties;

*Amendment*

(a) the nature of the risks related to the public interest objectives pursued, in particular the risks to consumers, ***service recipients, including patients,*** professionals or third parties;

## Amendment 21

### Proposal for a directive Article 7 – paragraph 1

*Text proposed by the Commission*

Member States shall, by appropriate means, ***inform citizens, service recipients, representative associations and*** relevant stakeholders ***other than the members of the profession*** before ***introducing*** new legislative, regulatory or administrative provisions restricting access to or pursuit of regulated professions, or amending existing ones, ***and give*** them the opportunity to make known their views.

*Amendment*

***In addition to members of the profession,*** Member States shall, by appropriate means, ***inform all*** relevant stakeholders ***including citizens, service recipients and representative associations*** before ***proposing*** new legislative, regulatory or administrative provisions restricting access to or pursuit of regulated professions, or amending existing ones, ***giving*** them the opportunity to make known their views, ***which shall then be given due consideration. That process may take place, for example, by means of a public consultation the results of which shall***

*inform the content of the provisions adopted.*

## Amendment 22

### Proposal for a directive Article 9 – paragraph 1

#### *Text proposed by the Commission*

1. The reasons for considering that provisions, assessed in accordance with this Directive, are justified, necessary and proportionate, and which are communicated to the Commission pursuant to paragraphs 5 and 6 of Article 59 of Directive 2005/36/EC, shall be recorded by the relevant competent authorities in the database of regulated professions, referred to in Article 59 paragraph 1 of Directive 2005/36/EC and thereafter made publicly available by the Commission.

#### *Amendment*

1. The reasons for considering that provisions, assessed in accordance with this Directive, are justified, necessary and proportionate, and which are communicated to the Commission pursuant to paragraphs 5 and 6 of Article 59 of Directive 2005/36/EC, shall be recorded ***expeditiously*** by the relevant competent authorities in the database of regulated professions, referred to in Article 59 paragraph 1 of Directive 2005/36/EC and thereafter made publicly available ***as soon as possible*** by the Commission.

## PROCEDURE – COMMITTEE ASKED FOR OPINION

<b>Title</b>	Proportionality test before adoption of new regulation of professions
<b>References</b>	COM(2016)0822 – C8-0012/2017 – 2016/0404(COD)
<b>Committee responsible</b> Date announced in plenary	IMCO 1.2.2017
<b>Opinion by</b> Date announced in plenary	ENVI 1.2.2017
<b>Rapporteur</b> Date appointed	Françoise Grossetête 5.4.2017
<b>Discussed in committee</b>	29.6.2017
<b>Date adopted</b>	12.10.2017
<b>Result of final vote</b>	+: 57 –: 1 0: 2
<b>Members present for the final vote</b>	Marco Affronte, Pilar Ayuso, Zoltán Balczó, Catherine Bearder, Ivo Belet, Biljana Borzan, Lynn Boylan, Paul Brannen, Soledad Cabezón Ruiz, Nessa Childers, Birgit Collin-Langen, Miriam Dalli, Angélique Delahaye, Mark Demesmaeker, Stefan Eck, José Inácio Faria, Karl-Heinz Florenz, Francesc Gambús, Elisabetta Gardini, Gerben-Jan Gerbrandy, Arne Gericke, Jens Gieseke, Julie Girling, Sylvie Goddyn, Françoise Grossetête, Andrzej Grzyb, Jytte Guteland, Jean-François Jalkh, Benedek Jávor, Karin Kadenbach, Urszula Krupa, Jo Leinen, Peter Liese, Norbert Lins, Rupert Matthews, Valentinas Mazuronis, Susanne Melior, Miroslav Mikolášik, Gilles Pargneaux, Piernicola Pedicini, Bolesław G. Piecha, Julia Reid, Daciana Octavia Sârbu, Annie Schreijer-Pierik, Renate Sommer, Ivica Tolić, Nils Torvalds, Adina-Ioana Vălean, Jadwiga Wiśniewska, Damiano Zoffoli
<b>Substitutes present for the final vote</b>	Herbert Dorfmann, Luke Ming Flanagan, Elena Gentile, Ulrike Müller, Christel Schaldemose, Bart Staes, Keith Taylor
<b>Substitutes under Rule 200(2) present for the final vote</b>	John Howarth, Răzvan Popa, Sven Schulze

## FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

57	+
ALDE	Catherine Bearder, Gerben-Jan Gerbrandy, Valentinas Mazuronis, Ulrike Müller, Nils Torvalds
ECR	Mark Demesmaeker, Arne Gericke, Julie Girling, Urszula Krupa, Rupert Matthews, Bolesław G. Piecha, Jadwiga Wiśniewska
EFDD	Piernicola Pedicini
ENF	Sylvie Goddyn, Jean-François Jalkh
GUE/NGL	Lynn Boylan, Stefan Eck, Luke Ming Flanagan
NI	Zoltán Balczó
PPE	Pilar Ayuso, Ivo Belet, Birgit Collin-Langen, Angélique Delahaye, Herbert Dorfmann, José Inácio Faria, Karl-Heinz Florenz, Francesc Gambús, Elisabetta Gardini, Jens Gieseke, Françoise Grossetête, Andrzej Grzyb, Peter Liese, Norbert Lins, Miroslav Mikolášik, Sven Schulze, Renate Sommer, Ivica Tolić, Adina-Ioana Vălean
S&D	Biljana Borzan, Paul Brannen, Soledad Cabezón Ruiz, Nessa Childers, Miriam Dalli, Jytte Guteland, John Howarth, Karin Kadenbach, Jo Leinen, Susanne Melior, Gilles Pargneaux, Răzvan Popa, Christel Schaldemose, Daciana Octavia Sârbu, Damiano Zoffoli
VERTS/ALE	Marco Affronte, Benedek Jávor, Bart Staes, Keith Taylor

1	-
EFDD	Julia Reid

2	0
PPE	Annie Schreijer-Pierik
S&D	Elena Gentile

Key to symbols:

+ : in favour

- : against

0 : abstention